United States
Environmental Protection
Agency

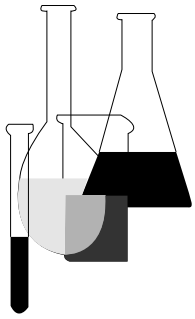
Prevention, Pesticides
and Toxic Substances
(7101)

EPA 712–C–96–272
February 1996

EPA

Occupational and Residential Exposure Test Guidelines

OPPTS 875.2900
Data Reporting and Calculations



INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

This guideline, along with the others in Series 875.2000 through 875.2900, is being substantially revised for publication in 1997. However, the current guidelines are still official. Before initiating any studies for post-application exposure registrants should contact EPA's Occupational and Residential Exposure Branch (within the Office of Pesticide Programs) at 703–305–6094.

Final Guideline Release: This guideline is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202–512–1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), internet: http://fedbbs.access.gpo.gov, or call 202–512–0132 for disks or paper copies. This guideline is also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher (gopher.epa.gov) under the heading ''Environmental Test Methods and Guidelines.''

OPPTS 875.2900 Data reporting and calculations.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP guideline 134.

(b) **Nondetectable residue method**—(1) **When used.** For purposes of this section, a reentry interval is that time period beyond which there are no detectable dislodgeable residues of the pesticide on surfaces to which the pesticide was applied, as indicated by studies conducted as described in OPPTS 875.2100 and 875.2200 of this guideline.

(2) **Approach.** Environmental samples may be collected periodically until no residues are detected in three consecutive samplings using suitably sensitive analytical techniques and equipment. Alternately, the applicant may be justified in extrapolating a dissipation curve to the minimum detectable levels. The interval for residue dissipation to the nondetectable level would be proposed as the reentry interval. For reentry intervals determined according to this approach, exposure information described in OPPTS 875.2400 and 875.2500 of this guideline are not required.

(c) **Allowable exposure level method**—(1) **When used.** For purposes of this section, a reentry interval is that time period beyond which dislodgeable residues on surfaces to which the pesticide was applied have dissipated to the allowable exposure level (AEL) (or lower) as indicated by studies described in OPPTS 875.2100, 875.2200, 875.2400, and paragraph (b) of this guideline.

(2) **Approach.** (i) Calculation of a reentry interval according to the criteria of paragraph (c)(1) of this guideline involves evaluation of data to determine that level of residue in a reentry site which will result in an amount of human exposure under specified human activities that is at or less than an AEL. To make this evaluation, the applicant should use two kinds of data:

(A) Data on the relationship between pesticide residue levels and total human exposure during an eight-hour period.

(B) Data on the relationship between pesticide residue levels and time.

(ii) For the approach outlined in paragraphs (c)(2)(i) of this guideline:

(A) The applicant will determine an AEL and described according to OPPTS 875.2000, paragraph (h), based on the toxicity data required by 40 CFR 158.340 and described by OPPTS Series 870 guidelines.

(B) The applicant will examine human exposure data to determine how much exposure (or what dose) a person would receive when performing activities (specific to the proposed use) in a treated area with specified levels of residues. These data will enable the applicant to determine a reentry level (Rs) for a particular combination of human activity, crop, pesticide formulation type, and site.

(C) Finally, the applicant will review residue dissipation curves to determine how long after application it will take the residue levels to decline to the reentry level in the particular study location, thus estimating the reentry interval (Ts).

(D) The number of sampling units in the study and all assumptions used in the calculations should be specified.

(d) **Adjustment to reentry intervals**—(1) **When used.** A registrant or registration applicant may provide information to support an adjustment of a reentry interval. Such information should be of one of the types described in paragraphs (d)(2) through (d)(4) of this guideline.

(2) **Adjustments based on toxicity studies.** The animal toxicity studies described in OPPTS Series 870 guidelines may have been performed using test substances of an end-use product or active ingredient in a solvent. Solvents may aid in dermal absorption of the pesticides and/or may increase their apparent toxicity. After application, such components of end-use products may dissipate from the application site more rapidly than the active ingredient. Testing of animals with the pesticide without solvents may show that it is not as toxic as the original product. If there are sufficient differences in toxicity or in residue retention after application, the applicant may wish to submit data to support adjustment of a reentry interval.

(3) **Adjustments based on residue dissipation studies.** In some cases, established reentry intervals are based on data developed from studies of a site that may not adequately characterize residue dissipation at another site because of regional and climatological differences, differences in application methods, or differences in post-treatment methods and exposure. These factors would likely affect the slope of the residue vs. time curve. In such cases, additional data may be submitted to the Agency to support an additional reentry interval.

(4) **Adjustments based on human exposure studies.** Data from human exposure studies may indicate significantly different human exposure levels because of widespread changes in agricultural practices or other conditions. Such data may be submitted to support adjustment of the reentry interval.

(e) **Early reentry: practices and limitations**—(1) **General.** Local conditions and activities may necessitate early reentry by individuals into

treated areas before the reentry period has completely elapsed. Such activities may include posting, scouting, crop sampling, and similar related activities, often of a brief and limited nature. Several practices may be necessary to protect individuals who must undertake early reentry. Some of these are described below. Consultation with local agricultural experts is generally recommended before early reentry is undertaken.

(2) **Reduction of site residues.** Site residues may be reduced to reentry level by rainfall or artificial means, such as spraying the site with water. Data on residue reduction by rainfall or equivalent spray washing (as in overhead irrigation) may be submitted to support early reentry. In those cases, early reentry may be granted to allow people to enter treated sites before expiration of the reentry interval.

(3) **Use of personal protective equipment.** Early reentry may be granted to allow people to enter treated sites before expiration of the reentry interval by use of personal protective equipment, such as protective clothing and appropriate respirators. The personal protective equipment should be appropriate for the pesticide residue levels at the site at the time of reentry and should conform to any existing protective standards (such as those established by OSHA). Data on the reduction of human exposure to residues by use of personal protective equipment should be submitted and support that the personal protective equipment would reduce human exposure to the AEL and would be likely to be used.

(4) **Reduced exposure times.** The reentry level is based on residue exposures representative of normal reentry activities for an 8-hour day. In circumstances where only respiratory exposure to airborne residue will occur, early reentry may be allowed for shorter periods at residue levels higher than the reentry level. The excursion factors described in the Threshold Limit Values (TLV) booklet of the American Conference of Governmental Industrial Hygienists (ACGIH) may be used. Excursion factors allow shorter exposures to chemicals at levels higher than the TLV or OSHA's Permissible Exposure Limit. This approach requires that the exposure level be within an acceptable excursion range and that the product of the concentration multiplied by the exposure time does not exceed the product of the TLV concentration multiplied by 8 hours. Such excursion factors are applied only to chemicals which do not have established ACGIH ''ceiling'' designations. The ceiling designations indicate that the TLV should not be exceeded.

(5) **Residue level test kits.** Early reentry may be allowed if field test kits establish that residues have dissipated to reentry level prior to expiration of the reentry interval. Data should be submitted to support the use of field test kit systems for monitoring pesticide residue levels. Such systems could include any of several chemical residue detection devices or procedures that would readily indicate when residue levels of treated

sites are greater or less than the AEL. (For this factor, the adjustment could either extend or shorten the reentry interval.)

(f) **References.** The following references should be consulted for additional background material on this test guideline. The following publications report procedures for the analysis of organophosphorus pesticide residues in the worker environment suitable for rapid tests in agricultural sites.

(1) Smith, C.A., F.A. Gunther, and J.D. Adams. 1976. Worker environment research. III. A rapid method for the semiquantitative determination of some dislodgeable pesticide residues on citrus foliage. Bull. Environ. Contam. Toxicol. 15:305-310. [This paper reported the use of a device for sampling foliar surface residues, and rapid methods for residue cleanup and quantification of organophosphorus pesticide residues. The method depends upon the generation of a color by reaction with 4(4-nitrobenzyl)pyridine.]

(2) Smith, C.A., and F.A. Gunther. 1978. Rapid estimation of organophosphorus pesticide residues in citrus grove soil. Bull. Environ. Contam. Toxicol. 19:571-577. [A procedure for field analysis of organophosphorus pesticide residues sorbed to surface soil is reported in this paper.]

(3) Berck, B., Y. Iwata, and F.A. Gunther. 1981. Worker environment research: Rapid field method for estimation of organophosphorus insecticide residues on citrus foliage and in grove soil. J. Agric. Food Chem. 29:209-216. [This paper is an elaboration of the studies in paragraphs (f)(1) and (f)(2) of this guideline using different sampling methodology and instrumentation. Procedures are reported for both foliar and soil residues.]

(4) Iwata, Y., J.B. Knaak, G.E. Carman, M.E. Dusch, and F.A. Gunther. 1982. Fruit residue data and worker reentry research for chlorthiophos applied to California citrus trees. J. Agric. Food Chem. 30:215-222. [This paper reports dissipation data for a pesticide and its five toxic alteration products and uses that data to estimate a reentry interval by the AEL and the CDFA methods. The authors report that both methods give the same reentry interval.]